Remarks

I. Introduction

Claims 40-47, 49, 50, and 73-90 are pending in the application, including independent claims 40, 78, 84, and 90. In the Office Action dated March 4, 2009, claims 40-47, 49, 50, and 73-90 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,080,191 ("Summers") in view of U.S. Pat. No. 5,522881 ("Lentz"), U.S. Pat. No. 5,123,917 ("Lee"), and U.S. Pat. No. 5,951,599 ("McCrory").

Applicant has carefully considered the Examiner's comments and respectfully disagrees with the Examiner's rejections. Applicant requests reconsideration and withdrawal of the rejections in light of the following remarks.

II. The Proposed Combination Does Not Render Independent Claims 40, 78, 84, and 90 Unpatentable.

Independent claims 40, 78, 84, and 90 were rejected as being unpatentable over Summers in view of Lentz, Lee, and McCrory. As amended, each of claims 40, 78, 84, and 90 recites in part:

> wherein a graft material is **secured to a support frame** by **folding one end of said graft material around one of said frame threads and along an inner surface of the support frame thereby having an area of double thickness of two layers of said same graft material** and affixing said two layers to each other without connecting said graft material to said one of said frame threads and **folding an opposite end of said graft material around another of said frame threads and along the inner surface of the support frame thereby having an area of double thickness of two layers of said graft material** and affixing said two layers to each other without connecting said graft material to said another of said frame threads, said two layers remaining affixed to each other even after said intraluminal support device is deployed in said body vessel.

The combination of Summers, Lentz, Lee, and McCrory as contemplated by the Examiner fails to disclose at least these elements.

In the present Office Action, the Examiner has acknowledged that Summers fails to disclose "the specific means of attaching the graft to the stent frame [recited in the claims]." Office Action dated March 4, 2009, p.2. That is, as detailed in Applicant's previous reply to the Office Action dated July 9, 2008, Summers fails to disclose securing a graft material to a support frame by **folding one end of the graft around one of the frame threads and along an inner surface of the support frame thereby having an area of double thickness of two layers of said graft material** and **affixing said two layers to each other without connecting said graft material to said one of said frame threads**. Summers also fails to disclose **folding an opposite end of said graft material around another of said frame threads and along the inner surface of the support frame thereby having an area of double thickness of two layers of said graft material** and **affixing said two layers to each other without connecting said graft material to said another of said frame threads**. Further, Summers fails to disclose securing a graft material to a support frame by affixing two layers of the same graft material to each other such that the **two layers remain affixed to each other even after said intraluminal support device is deployed in said body vessel**, as recited in amended claims 40, 78, 84, and 90.

In an effort to cure Summers' deficiencies, the Examiner has cited Lentz. However, Lentz also fails to disclose, and actually teaches away from the above-recited elements of amended claims 40, 78, 84, and 90. Accordingly, Applicant respectfully submits that the combination of Lentz, Summers, Lee, and McCrory as contemplated by the Examiner is improper and the rejection should be withdrawn.

Lentz is directed to an implantable **tubular prosthesis** having "free standing" integral cuffs 20 and 22 disposed at opposite ends. Col. 4, lines 4-10. The free standing cuffs are formed by folding the ends of the tubular conduit (a full graft) back externally over itself. *Id.* Each free standing cuff includes

"inwardly directed **open ends** 20a and 22a respectively **which are wholly unobstructed for stent insertion**. **Open ended slots** 24 and 26 are defined between the external surface of tubular conduit 12 and the internal surface of cuffs 20 and 22." Col. 4, lines 15-20. **Each of the slots** 24 and 26 is configured to receive **one or more stents**, which provide a support structure that seals the prosthesis against a body vessel. Col. 4, lines 20-23. There is no evidence in the Figures or specification that the open ends of the cuffs are ever sealed or attached to the graft. Indeed, Figures 2 and 4, as well as the specification actually teach the opposite. Lentz explicitly states that the stents may be positioned **either before or after the prosthesis has been implanted in a patient's blood vessel**, thus the cuffs **must remain open**, even after implantation within a body vessel. Col. 4, lines 43-56. Moreover, Lentz also states, "If it is determined that a more appropriately sized stent is necessary for a proper seal after insertion, the stent can be easily removed and replaced within the cuff by a better fitting stent without first excising the prosthesis." Col. 5, lines 17-28. If the folded portion of the cuff were secured to the tubular prosthesis it would be impossible for the stents to be inserted or removed after implantation. Thus, it is clear that the free standing cuffs disclosed by Lentz must be left open to allow for stent insertion and removal after the prosthesis has been implanted. Accordingly, Lentz actually teaches away from securing a graft to a support frame at all.

In contrast, claim 40 requires **securing a graft to a support frame** by **folding one end of a graft around two frame threads disposed at opposite ends of the support frame and along an inner surface thereof thereby having an area of double thickness of two layers of the graft material** and **affixing the two layers to each other without connecting the graft material to the frame threads**. Initially, Applicant notes that Lentz does not disclose folding a graft over a frame thread of a **single stent**; Lentz clearly discloses inserting at least two stents, one stent per cuff. Moreover, as shown in Figures 4 and 6, the graft is never folded over any portion of the stent to create an area of double thickness of two layers of the graft. Indeed, as discussed above, to do so

would prevent the stents from being inserted into or removed from the cuffs after implantation.

Additionally, the free standing structure of the cuffs disclosed by Lentz is only possible **because the prosthesis is a tubular full graft**. That is, because the tubular conduit is a full tube, the tube radially restrains the folded portion of the ends and allows them to be everted to produce a free standing cuffed configuration. Achieving a free standing cuffed configuration in this manner is impossible for a partial graft, which is essentially a mono-planar piece of graft material, because it lacks the structure necessary to provide such circumferential restraint.

Furthermore, as the Supreme Court noted in *KSR*, in assessing obviousness one should consider the reasons that would have prompted a person of ordinary skill in the relevant art to combine the elements as in the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Examiner has identified no reason why a person of ordinary skill would look to combine Lentz' full tubular graft having free standing cuffs with open, unattached ends with Lee, which discloses methods of attaching graft material to itself, or McCrory, which teaches partial stent-grafts. In short, the only possible reason to combine these references comes from the present application. In other words, this combination is the result of improper hindsight bias. *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552-53 (Fed. Cir. 1983); MPEP § 2141.01(III).

Furthermore, even if Lentz were combinable with Summers, McCrory, and Lee, such modification would change its principle of operation, which is to provide a full graft that allows individual stents to be inserted and removed from the free standing open cuffs **even after implantation in a body vessel**. Such modifications are improper and cannot form the basis for prima facie obviousness. MPEP § 2143.01.

Like Summers and Lentz, as detailed in Applicant's response to the previous Office Action, Lee and McCrory also fail to teach or suggest a graft

material secured to a support frame by folding one end of said graft material around one of said frame threads and along an inner surface of said support frame thereby having an area of double thickness of two layers of said same graft material and affixing said two layers to each other without connecting said graft material to said one of said frame threads and folding an opposite end of said graft material around another of said frame threads and along said inner surface of said support frame thereby having an area of double thickness of two layers of said graft material and affixing said two layers to each other without connecting said graft material to said another of said frame threads, said two layers remaining affixed to each other even after said intraluminal support device is deployed in said body vessel, as recited in amended claims 40, 78, 84, and 90. For at least these reasons, and because the proposed combination of Summers, Lentz, Lee, and McCrory is improper, the combination of Summers, Lentz, Lee, and McCrory as contemplated by the Examiner does not render independent claims 40, 78, 84, and 90, or any claim that depends therefrom, unpatentable.

VII. Conclusion

Applicant submits that Lentz is not combinable with Summers, Lee, and McCrory, and accordingly the combination thereof is improper. Applicant hereby submits that the claims, as amended, patentably distinguish over the art of record. Applicants earnestly request expedited consideration and allowance of this application.

Respectfully submitted,

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